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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,484	05/07/2001	Bernhard Fischer	37974-0156	1519
26633	7590	10/05/2004	EXAMINER	
HELLER EHRMAN WHITE & MCAULIFFE LLP 1666 K STREET,NW SUITE 300 WASHINGTON, DC 20006			ROBINSON, HOPE A	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/849,484

Applicant(s)

FISCHER ET AL.

Examiner

Hope A. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-62 is/are pending in the application.
- 4a) Of the above claim(s) 57-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 44-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/7/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response to the Office Action mailed July 8, 2003 on July 13, 2004, March 22, 2004 and December 23, 2004 is acknowledged.
2. Claims 1-43 and 63 have been canceled. Claims 44, 47-48, 51 and 55-58 have been amended. Claims 44-62 are pending. Claims 44-56 are under examination.
3. The amendment filed on July 13, 2004 amended claim 57 which was directed to "A method of recovering a stable Factor VIII/vWF-complex" and presented a claim directed to "A method of providing a stable a Factor VIII/vWF-complex". Amended claim 57 is drawn to a method that differs from the method originally presented in the application in the method steps and the endpoint. Note that the claim was examined as a recovery method or the isolation of the complex, hence the citation of a reference that teaches an extraction process for the Factor VIII/vWF-complex. Note also that a rejection was made under 35 U.S.C. 112, second paragraph with regard to Factor VIII being present in the claim as a separate product. The claim as presently amended is directed to a preparation which includes the Factor VIII in an admixture leading to the production of a Factor VIII/vWF-complex, but not necessarily the recovery of said product as examined previously. Therefore, since the method claims as amended are directed to an invention that is independent or distinct from the invention originally claimed for the reasons indicated above and since applicant has received an action on

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the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. The amended claims would have been subjected to a Restriction Requirement had they been presented at the time of filing. Therefore, claims 57-62 are withdrawn.

4. The following grounds of objection/rejection are or remain applicable :

Claim Objection

5. For clarity it is suggested that claim 44 is amended to recite "protein solution contaminated with other proteins" instead of "protein solution that also contains contaminating proteins". In addition for clarity the claim should be amended to recite "calcium with an elution salt concentration", instead of "calcium at an elution salt concentration".

Drawings

6. The Drawings filed on August 8, 2001 are objected to because some of the images are blurred, see for example Fig. 1. Applicant is reminded to file formal drawings when notified of allowable subject matter.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 44-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 and the dependent claims hereto are indefinite for the recitation "no more than 200 mM and and a calcium salt", as the word "and" is written twice in the claim. In addition, claim 44 as amended is indefinite because it is unclear if complex or the elution salt is absent calcium. See for example, page 19 of the instant specification, which discloses "a buffer system free from CaCl_2 ."

8. Applicant's arguments filed on July 13, 2004, March 22, 2004 and December 23, 2004 have been considered. The objection to the specification, IDS and priority has been withdrawn. Note that new grounds of rejections have been instituted based on amendments to the claims, therefore, the claims remain rejected under 35 U.S.C. 112, first paragraph. The rejection under 35 U.S.C. 102 of record has been withdrawn in view of the amendments to the claims that changed the invention originally presented.

Conclusion

9. No claims are allowable.

10. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

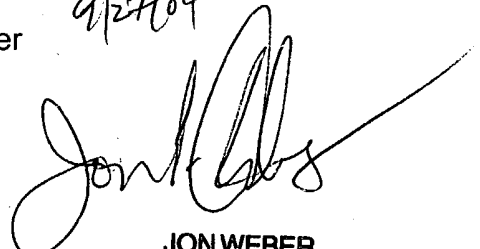
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS ~~1A~~

Patent Examiner

9/27/04

JON WEBER
SUPERVISORY PATENT EXAMINER